King, Valerie A.

From: Oey, Jan
Sent: Monday, July 08, 2002 12:31 PM
To: Osborne, Kevin (PMMC Legal)
Cc: King, Valerie A.; Roethig, Hans; Nelson, Christopher (PMMC)
Subject: Review of protocol and informed consent for the Accord menthol clinical study

Dear Kevin,

I am attaching a protocol, protocol attachment, and an informed consent for your review.

Since the study design is the same as that of the other short term Accord study, a word-for-word comparison of protocols has been made and checked for consistency. This comparison is also attached.

But, this comparison cannot be done for the informed consent because each Investigational Review Board (IRB) requires a specific format. Needless to say, we have checked it for consistency with previous informed consents.

PAREXEL in Baltimore has a window set for this study for September 3 to 26. The next one is mid November to mid December, which would be too late to have results for the overall Accord plan. Thus, we must take the September window and must submit all documents for IRB review by today. I know it is impossible to have your comments by today. Therefore, our plan is to let the documents be submitted today, but to submit substantial changes, if any, in an amendment to the IRB at July 29.

Best regards,
Jan


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2_Philip Morr...


Protocol Compare
Menthol v JLI...


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